

a cell membrane, or both.

43. (Amended) The [polypeptide]immunoadhesin of claim 30, wherein the polypeptide has at least one native amino acid glycosylation site substituted or deleted [unaccompanied by native glycosylation].

44. (Amended) The [polypeptide]immunoadhesin of claim 30, wherein the polypeptide is glycosylated with a ratio of sugars that differs from [which is glycosylated in a pattern other than] native glycosylation.

REMARKS

Formal Matters

The specification is amended merely to correct inadvertent typographical errors. Support for the amendments on page 54 are supported by the preceding paragraphs (page 53, line 27 to page 54, line 21) describing construction of various immunoadhesin. No new matter is added by these amendments. The Examiner is respectfully requested to enter them.

Claims 30-32 and 40-44 are pending in the application. Claims 30 and 39-44 are amended to more particularly point out and distinctly claim the subject matter of the invention, and to narrow the scope of the issues on appeal should an appeal become necessary.

Support for the claim amendments is found throughout the originally filed specification, such as at page 9, line 17; page 20, lines 18-24; page 22, lines 23-24; page 39, lines 5-16; page 51, line 11 to page 52, line 9; and page 79, lines 12-15.; Figs. 1, 2, 3, 4A, and 4B and the figure legends for these figures; and in SEQ ID NO: 1, 5, and 22.

No new matter is added by these amendments and the Examiner is respectfully requested to enter them.

Information Disclosure

Applicants wish to bring to the Examiner's attention the issuance of U.S. Patent No. 5,912,326 to Han Chang issued June 15, 1999 (filed September 8, 1995), which claims priority to the same application as WO 97/09425, which PCT publication was made of record as item 8 in the IDS filed in this application. Applicants submit that the information disclosed in the '326 patent is cumulative. If the Examiner considers it necessary to have the '326 made of record by Applicants

in an IDS, Applicants will do so at the Examiner's request. A copy of the '326 patent is enclosed for the Examiner's convenience.

Withdrawal of Rejections

Applicants gratefully acknowledge withdrawal of the rejections of claims 29-32 under section 112, first and second paragraphs, section 102(b), and section 102(e).

New Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 31-32, 39-41, and 43-44 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the various reasons discussed in the paragraphs below. Applicants respectfully traverse each reason for rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

The recitation of "immunoglobulin sequence" in claim 31 is rejected for lack of antecedent basis in independent claim 30 from which claim 31 depends. Applicants respectfully point out that the term "immunoadhesin" recited in claim 30 includes within its definition of an immunoglobulin sequence at page 34, lines 16-23 of the specification. Without acquiescing to the rejection and merely to expedite prosecution, claim 30 is amended to recite an immunoglobulin sequence. Withdrawal of the rejection is respectfully requested.

The rejection of claim 41 for reciting "ATCC deposit 209155" is moot because the claim has been amended to recite a nucleic acid sequence identification number.

Claims 39-41 are amended to more particularly point out and distinctly claim the subject matter of the invention by reciting the nucleic acid sequence within the mouse and human NRG3 nucleic acid sequences encoding the EGF-like domain. Support for the amendment is found throughout the specification, such as in Figs. 1, 2, 3, 4A, and 4B, and in the nucleic acid sequences SEQ ID NO: 1, 5, and 22.

Claims 43-44 recited the term "native glycosylation," which the Examiner suggests to be indefinite. Applicants respectfully disagree and point to support in the specification to define the term. For example, native glycosylation, a variant glycosylation pattern, or unglycosylated EGF-like domain of NRG3 is disclosed at page 9, line 17; page 20, lines 18-24; page 22, lines 23-24; page 39,

lines 5-16; page 51, line 11 to page 52, line 9; and page 79, lines 12-15. Without acquiescing to the rejection and merely to expedite prosecution, claims 43 and 44 are amended to recite that at least one native amino acid glycosylation site is substituted or deleted (claim 43) or that non-native glycosylation refers to sugar ratios that differ from the native NRG3 (claim 44).

In view of the above discussion, Applicants respectfully submit that the rejection under 35 U.S.C. § 112, second paragraph, is overcome. Withdrawal of the rejection and allowance of the claims is respectfully requested.

New Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 39-41 are rejected as allegedly containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The rejection applies to information regarding the deposit of nucleic acid sequences in ATCC deposits 209156, 209157, and 209297. Applicants respectfully traverse the rejection by pointing out that the Figures and the Sequence Listing contain the recited nucleic acid sequences, and by demonstrating that the necessary deposits have been made.

The nucleic acid sequences SEQ ID NO: 1, 5, and 22 in the Sequence Listing and in Figures 1, 2, 3, 4A, and 4B provide the sequences referred to in claims 39-41. Thus, the sequence information is provided in the specification.

Although claims 39-41 are amended to recite a SEQ ID number, the ATCC deposits provide additional sources for the sequences. The ATCC deposits 209156, 209157, and 209297 were correctly deposited under the terms of the Budapest Treaty as demonstrated by the enclosed ATCC deposit records.

Claims 43-44 were rejection under 35 U.S.C. § 112, first paragraph, as allegedly claiming subject matter not described in the specification such as to convey to one skilled in the art that the inventors possessed the claimed invention. Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims. The Examiner suggested that recitation of the written support within the specification would resolve the issue. Applicants assume that the term "radical interceptor" in the last line of this rejection is a typographical error (see the last line of the third paragraph on page 6 of the Office Action). Applicants pointed to the recitations regarding

non-native glycosylation in the specification is support of an argument against a section 112, second paragraph rejection to claims 43 and 44, above. Specifically, support is found throughout the specification, such as at page 9, line 17; page 20, lines 18-24; page 22, lines 23-24; page 39, lines 5-16; page 51, line 11 to page 52, line 9; and page 79, lines 12-15. Withdrawal of the rejection is respectfully requested.

In view of the above discussion, Applicants respectfully submit that the rejection has been overcome and the claims are in condition for allowance, which action is respectfully requested.

SUMMARY

Claims 30-32 and 39-44 are pending in the application. Previously pending claims 30 and 42 were allowed. Claim 30 is amended merely to provide antecedent basis for claim 31.

New rejections under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 112, first paragraph are overcome as discussed above.

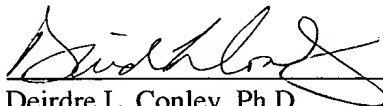
Amendments to the claims are made merely to narrow the issues on appeal, should an appeal become necessary, and to more particularly point out and distinctly claim the subject matter of the invention. Entry of the amendments is respectfully requested.

Applicants submit that the rejections are overcome and that the claims are in condition for allowance, which action is respectfully requested.

This document is submitted with a transmittal letter, Notice of Appeal, petition for a two-month extension of time, and authorization to withdraw fees from our Deposit Account No. 07-0630. In the unlikely event that this document is separated from the transmittal letter, Applicants hereby petition the Commissioner to authorize charging our Deposit Account No. 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Respectfully submitted,
GENENTECH, INC.

Date: December 18, 2000

By: 
Deirdre L. Conley, Ph.D.
Reg. No. 36,487
Telephone No. (650) 225-2066



09157

PATENT TRADEMARK OFFICE

PENDING CLAIMS, December 18, 2000

30. An immunoadhesin comprising a polypeptide and an immunoglobulin amino acid sequence, the polypeptide comprising an amino acid sequence of the EGF-like domain of SEQ ID NO:4, wherein the polypeptide binds to ErbB4 receptor and activates receptor tyrosine phosphorylation of the ErbB4 receptor.

31. The immunoadhesin of claim 30 wherein the immunoglobulin sequence is an immunoglobulin heavy chain constant domain sequence.

32. The immunoadhesin of claim 31 wherein the immunoglobulin sequence is a constant domain sequence of an IgG-1, IgG-2 or IgG-3.

39. The immunoadhesin of claim 30, wherein the polypeptide is encoded by a nucleic acid sequence comprising nucleic acids 1150 to and including 1290 of the NRG3 nucleic acid open reading frame sequence SEQ ID NO:1.

40. The immunoadhesin of claim 30, wherein the polypeptide is encoded by a nucleic acid sequence comprising nucleic acids 999 to and including 1139 of the NRG3 nucleic acid open reading frame sequence SEQ ID NO:5.

41. The immunoadhesin of claim 30, wherein the polypeptide is encoded by a nucleic acid sequence comprising nucleic acids 856 to and including 996 of the NRG3 nucleic acid open reading frame sequence SEQ ID NO:22.

42. The immunoadhesin of claim 30, wherein the polypeptide is devoid of a cytoplasmic domain, or devoid of a transmembrane domain that can anchor the polypeptide in a cell membrane, or both.

43. The immunoadhesin of claim 30, wherein the polypeptide has at least one native amino acid glycosylation site substituted or deleted.

44. The immunoadhesin of claim 30, wherein the polypeptide is glycosylated with a ratio of sugars that differs from native glycosylation.




DEC 28 2000

TECH CENTER 1600/2900

Patent Docket P1084R1-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Paul J. Godowski et al. Serial No.: 09/107,979 Filed: June 30, 1998 For: ErbB4 RECEPTOR-SPECIFIC NEUREGULIN RELATED LIGAND ANTIBODIES AND USES THEREFORE (as amended)	Group Art Unit: 1645 Examiner: L. Lee <div style="border: 1px solid black; padding: 5px;"><p style="text-align: center;">CERTIFICATE OF MAILING</p><p><small>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on</small></p><p style="text-align: center;">December 18, 2000</p><p style="text-align: center;"> Pamela Gavette</p></div>
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STATEMENT OF DEPOSIT UNDER THE BUDAPEST TREATY

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Deposit of biologically pure genetic material as the following plasmids were made under the Budapest Treaty with the American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

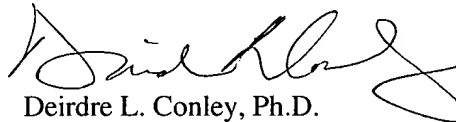
Genetic Material	ATCC Number	Deposit Date
Plasmid pLXSN.mNRG3	209156	July 22, 1997
Plasmid pRK5.tk.neo.hNRG3B1	209157	July 22, 1997
Plasmid pRK5.tk.neo.hNRG3B2	209297	September 23, 1997

Access to said material will be available during the pendency of the patent application to one determined by the Commissioner of the United States Patent and Trademark Office to be entitled thereto under 37 C.F.R. §1.14 and 35 U.S.C. §122, or if and when such access is required by the Budapest Treaty. All restrictions on availability of said cultures will be irrevocably removed upon the granting of a patent based upon the application and said cultures will remain permanently available for a term of at least five

years after the most recent request for the furnishing of samples and in any case for a period of at least 30 years after the date of the deposit. Applicant avers that they will replace the deposited biological material should the cultures become nonviable.

Respectfully submitted,
GENENTECH, INC.

Date: December 18, 2000



Deirdre L. Conley, Ph.D.
Reg. No. 36,487

1 DNA Way
So. San Francisco, CA 94080-4990
Phone: (650) 225-2066
Fax: (650) 952-9881

PCDoc # 83451



American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 908-768 ATCCROVE • FAX: 301-816-4366

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Genentech, Inc.
Attn: Sean A. Johnston
1 DNA Way
So. San Francisco, CA 94080

RECEIVED
AUG 06 1997
GENENTECH, INC.
LEGAL DEPT.

Deposited on Behalf of: Genentech, Inc. (Ref. Docket P1084)

Identification Reference by Depositor:

ATCC Designation

Plasmid pRK5.tk.neo.hNRG3B2
Plasmid pLXSN.mNRG3
Plasmid pRK5.tk.neo.hNRG3B1

209155
209156
209157

The deposits were accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposits were received July 22, 1997 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested July 30, 1997. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: July 30, 1997

cc: Deirdre L. Conley



AMERICAN TYPE CULTURE COLLECTION

12301 Parklawn Drive
Rockville, Maryland 20852 USA

Telephone: 301/231-5519

FAX: 301/816-4366

DC/45

FACSIMILE

Date: July 30, 1997

To: Deirdre L. Conley
Genentech, Inc.

Fax Number: 1-415-952-9881

Total number of pages including this page: One (1)

From: ATCC Patent Depository

PR1084

Reference: Patent Deposit on behalf of Genentech, Inc. (Ref. Docket P1084).

Plasmid pRK5.tk.neo.hNRG3B2 assigned ATCC 209155,
Plasmid pLXSN.mNRG3 assigned ATCC 209156, and
Plasmid pRK5.tk.neo.hNRG3B1 assigned ATCC 209157.

Date of deposit July 22, 1997. Paperwork will be forwarded to you in a few days.

An invoice will be sent under separate cover as follows:

One time fee - 30 years	\$ 1,800.00
Informing of Requesters	1,080.00
Viability Test	<u>450.00</u>

Total amount due to ATCC 209155-209157

\$ 3,330.00

Barbara M. Hailey, Administrator, ATCC Patent Depository
Telephone: 301/231-5519

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Also,
Have you moved? Our file address for Genentech
is 460 Point San Bruno Blvd., not 1 DNA Way. Please clarify.
BMA



American Type Culture Collection

12201 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Genentech, Inc.
Attn: Janet E. Hasak
1 DNA Way
So. San Francisco, CA 94080-4990

Deposited on Behalf of: Genentech, Inc.

Identification Reference by Depositor:

ATCC Designation

prK5B-based plasmid DNA27865-1091 (Ref. Docket No. PR1091)	209296
Plasmid prK5.tk.neo.hNRG3B2 (Ref. Docket No. P1084rl and PR1084)	209297

The deposits were accompanied by: ___ a scientific description ___ a proposed taxonomic description indicated above.

The deposits were received September 23, 1997 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested October 6, 1997. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: October 6, 1997

cc: Deirdre L. Conley



AMERICAN TYPE CULTURE COLLECTION
12301 Parklawn Drive
Rockville, Maryland 20852 USA

Telephone: 301/231-5519
FAX: 301/816-4366

FACSIMILE

Date: October ⁷~~6~~, 1997

To: Deirdre L. Conley
Genentech, Inc.

Fax Number: 1-650-952-9881

Total number of pages including this page: One (1)

From: ATCC Patent Depository

Reference: Patent Deposit on behalf of Genentech, Inc. (Ref. Docket No. PR1091)

pRK5B-based plasmid DNA27865-1091 (Ref. Docket No. PR1091) assigned ATCC 209296, and

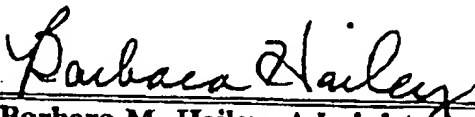
Plasmid pRK5.tk.neo.hNRG3B2 (Ref. Docket No. P1084rl and PR1084) assigned ATCC 209297.

Date of deposit September 23, 1997. Paperwork will be forwarded to you in a few days.

An invoice will be sent under separate cover as follows:

One time fee - 30 years	\$ 1,200.00
Informing of Requesters	720.00
Viability Test	<u>300.00</u>

Total amount due to ATCC 209296-209297 \$ 2,220.00


Barbara M. Hailey, Administrator, ATCC Patent Depository
Telephone: 301/231-5519

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